

REMARKS

Claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 143-189 are pending and under examination. Claims 1, 65 and 90 have been amended. Support for the amendments can be found throughout the specification and the claims as filed. In particular, support for the amendment to claims 1, 65 and 90 can be found, for example in original claims 3 and 5. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Applicants appreciate Examiner Zeman's time and helpful discussion with Applicants' representative in the telephonic interview conducted May 22, 2008. It is believed that the response addresses the issues discussed in the interview.

Regarding the Information Disclosure Statement submitted herewith, it is pointed out that the application corresponding to Patent No. 7,343,247, issued March 11, 2008, cited on the Information Disclosure Statement, was previously made of record in the Information Disclosure Statement filed January 5, 2004, as U.S. publication 2002/0095259.

The rejection of claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 143-189 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter is respectfully traversed. With respect to claim 143, this rejection has been rendered moot by the cancellation of this claim. With respect to the remaining claims, Applicants respectfully maintain, for the reasons of record, that the claims are directed to statutory subject matter.

Applicants appreciate the guidance provided by Examiner Zeman to Applicants' representative in the telephone interview on March 22, 2008, on considerations of possible claim language to address this rejection. Consistent with the discussion during the interview, independent claims 1, 65 and 90 have been amended to recite the step of contacting a specimen from an individual with a target. It is pointed out that independent claim 144 recites in step (d) "contacting a leukocyte specimen from an individual with a target." Per the discussion with Examiner Zeman in the telephone interview, it is believed that a claim reciting such a "wet" step would be considered statutory subject matter.

With regard to claim 138, this claim is directed to a computer apparatus and clearly falls under the category a “machine” as set forth in 35 U.S.C. § 101. Therefore, claim 138 is directed to statutory subject matter. Regarding claim 141, this claim is directed to a computer-readable medium having stored thereon instructions which, when executed by a processor, cause the processor to perform the recited steps. As set forth in MPEP § 2106.01 (I), “a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program’s functionality to be realized, and is thus statutory” [emphasis added]. Thus, claim 141 is directed to statutory subject matter.

Applicants respectfully maintain that the claims are directed to statutory subject matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claims 1, 6-9, 11, 13, 15, 16, 65, 70-80, 90, 95-104, 138, 139, 141 and 143-189 under 35 U.S.C. § 101 and § 112, first paragraph, as allegedly lacking utility is respectfully traversed. With respect to claim 143, this rejection has been rendered moot by the cancellation of this claim. With respect to the remaining claims, Applicants respectfully maintain that the claims have a specific, substantial and credible utility.

Applicants appreciate Examiner Zeman’s comments to Applicants’ representative in the telephone interview relating to the utility rejection. Independent claim 1 is directed to a method of determining a comparative expression profile, in which a reference expression profile or perturbed expression profile is determined. Independent claim 65 is directed to a method of diagnosing a health state, in which a reference health state or disease state is determined. Independent claim 90 is directed to a method of diagnosing a health state, in which a reference health state or perturbed health state is determined. Independent claim 144 is directed to a method of diagnosing a health state, in which a reference health state or perturbed health state is determined.

In the Office Action, it is asserted that the specification does not disclose any information about “health-associated” reference individuals and/or what the “health-associated” reference indicates. Contrary to the assertion in the Office Action, the specification does teach the meaning of these terms. For example, the specification teaches that a “health-associated

reference expression region” refers to a region of multidimensional space that is representative of the expression levels of a sample of molecules in a population of reference individuals (page 20, lines 20-24). The specification further teaches that a “reference individual” refers to an individual selected for comparison using defined criteria such as being healthy or having a desired characteristic such as gender, ethnic background, presence of a disease, or other desired criteria for comparing the health state of an individual (page 22, lines 8-25). The specification additionally teaches that, once a reference criteria has been identified, a population of individuals having the desired criteria is selected, for example, a reference population of healthy individuals (page 22, line 26, to page 23, line 12). The specification also provides further teaching on the selection of a reference population (page 70, line 1, to page 74, line 16). Thus, the specification provides clear teaching of the meaning of a reference individual and reference population and the meaning of a health-associated reference expression region.

Moreover, it is clear based on the teaching in the specification that selection of a reference population for comparison of an individual allows the determination of whether the individual has expression levels of molecules that, as represented by a multidimensional coordinate point, fall within the health-associated expression region, that is, have expression levels that fall within the expression levels of the reference population. Alternatively, if the expression levels of molecules of an individual, as represented by the multidimensional coordinate point, lie outside the health-associated expression region, the individual has an expression profile that differs from the reference population. Such a difference is reflected as a “perturbed” health state. As taught in the specification, a “perturbed expression profile” refers to a characteristic representation of the expression state of a sample of molecules of a population that falls outside a health-associated reference expression region (page 28, lines 15-18). Furthermore, a “perturbed health state” refers to the health state of an individual having a perturbed expression profile, that is, expression levels that lie outside of the health-associated expression region for those molecules (page 29, lines 18-24).

The specification additionally teaches that the methods can be used to diagnose a disease or the health state of an individual (page 11, lines 16-29). For example, the specification teaches that an individual having molecules with expression levels outside a health-associated reference region has a perturbed health state, which can be correlated with a disease (page 11, lines 26-29).

The specification further teaches that the methods can be used to diagnose a disease, determine the prognosis of a disease, or predict the course of a disease, as well as numerous exemplary diseases (page 9, line 13, to page 10, line 2). It is clear to one skilled in the art that knowledge of whether an individual has expression levels that indicate the same health state as a reference population or a perturbed health state is useful in determining the health state of an individual. Thus, contrary to the assertion in the Office Action, Applicants respectfully maintain that the claimed methods have a specific, substantial and credible utility of determining whether an individual has expression levels of molecules that correlate with a reference population such as a healthy population or whether the expression levels indicate a perturbed health state, which can be correlated with a disease. Accordingly, Applicants respectfully maintain that the claimed methods have a specific, substantial and credible utility. Therefore, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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